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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/080,504	02/22/2002	Olaf Reinhold	030903.0004.UTL	8672

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EXAMINER	
LEWIS, AARON J	

ART UNIT	PAPER NUMBER
3743	

DATE MAILED: 07/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/080,504	REINHOLD ET AL.	
	Examiner	Art Unit	
	AARON J. LEWIS	3743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04/08/2004 (AMENDMENT)*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1-8,10-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stimpson et al. ('416) in view of Michaels et al. ('854).

As to claim 1, Stimpson et al. disclose a device for delivering an aerosolized compound, the device comprising: a reservoir (L) that stores the compound; a system comprising an entry port (68) and an element (62) to generate particles of a desired size for ejection from an ejection head of the element (fig.8a), wherein said particles comprise a compound (col.3, lines 23-28), and wherein said system is fluidly connected to a reservoir; and a housing (43,44) comprising an inlet (68) and an outlet (81) between which is formed an airflow path and in which at least the ejection head is disposed in the air flow path (see arrows indicating air flow path in fig.7a) downstream of the inlet and upstream from the outlet, wherein the housing provides for a substantially unobstructed airflow between the ejection head and the outlet when air traverses the airflow path from the inlet to the outlet.

The difference between Stimpson et al. and claim 1 is physical ejection through one or more apertures from an ejection head.

Michaels et al., in a device for delivering an aerosolized compound, teach physical ejection through one or more apertures from an ejection head for the purpose of controlling the size of aerosolized particles and controlling the depth of deposition within a patient's respiratory tract (col.4,lines 1-62).

It would have been obvious to modify the manner of generating aerosol particles of Stimpson et al. to employ a ejection head head having a plurality of apertures because it would have provided a means for controlling the size of aerosolized particles and controlling the depth of deposition within a patient's respiratory tract as taught by Michaels et al..

As to claims 2 and 3, the compound (col.3, lines 23-28) is a pharmaceutical compound and is stored in the reservoir in a liquid formulation (L).

The difference between Stimpson et al. and claim 4 is the particular type of drug being delivered.

Michaels et al., in a device for delivering an aerosolized compound, teach the use of a variety of drugs including proteins, hormones and drugs which fall into the category of small molecules (col.2, lines 11-20 and col.6, lines 5-13) for the purpose of treating a variety of ailments.

It would have been obvious to delivery a variety of drugs using the device of Stimpson et al. including proteins, hormones and small molecules because it would have provided a means for treating a variety of respiratory ailments as taught by Michaels et al..

Claims 5-7 are included in Stimpson et al. as modified by Michaels et al. for the reasons set forth above with respect to claim 4. As to the recited gene delivery vehicle in claim 7, it is submitted that nebulizer of Stimpson et al. alone and as modified by Michaels et al. is fully capable of nebulizing liquid medicaments which are aerosolizable and inhalable including a medicament which is a gene delivery vehicle.

As to claim 8, the reservoir and particle generating system (50) of Stimpson et al. are disposed within the housing (43,44).

As to claim 10, the reservoir of Stimpson et al. is illustrated as being detachable (figs.3,3a,6,7) from the housing.

As to claim 11, the reservoir and particle generating system are integrated into a single detachable unit (fig.8).

As to claims 12-14, the particle generation system (62) of Stimpson et al. (col.5, lines 28-57) is an electronic piezoelectric ejection device which also uses heat to generate particles ejected from its head.

As to claims 15-17, the particles generated by Michaels et al. are of a size that allows the particles to transit to and be deposited in alveoli (col.4, lines 23-26). The particular particle diameter is dependent upon the selected pore diameter of a given porous body (col.4, line 4); consequently, the particle diameter can be arrived at through mere routine obvious experimentation and observation. The determining factor in the selection of a given porous body having a particular pore size as taught by Michaels et al. is the intended depth of deposition within a patient's respiratory system.

As to claim 18, the unobstructed airflow in Stimpson et al. is illustrated as being substantially laminar (see arrows indicating airflow through mouthpiece 24) prior to exiting the housing outlet (fig.7a).

As to claim 19, the substantially unobstructed airflow in Stimpson et al. (e.g. fig.7a) comprises a substantially homogeneous mixture of the ejected compound and air (from inlet 68) in the airflow prior to exiting the housing outlet (81).

Claims 21 and 23 are substantially equivalent in scope to claim 1 and are included in Stimpson et al. for the reasons set forth above with respect to claim 1. Additionally, Stimpson et al. illustrate air flow with arrows (70) in fig.7a. The airflow illustrated by these arrows inherently indicates substantially unobstructed airflow as well as substantially non-turbulent airflow when air traverses the airflow path from the inlet to the outlet. As to the generation of particles by physical ejection through one or more apertures of an ejection head, Michaels et al. teach the generation of particles by physical ejection through one or more apertures of an ejection head (col.4, lines 1-62).

As to claim 22, Stimpson et al. (fig.7a) illustrates air being drawn from inlet (68) to outlet (81).

As to claim 24, the airflow in Stimpson et al. (fig.7a) between the ejection head (62) and outlet (81) is illustrated as being substantially laminar (see airflow arrows in mouthpiece 24).

3. Claims 9 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stimpson et al. ('416).

As to claim 9, the shape of the reservoir of Stimpson et al. includes curved surfaces which conduct airflow therethrough in an efficient manner; consequently, these curved surfaces are readable upon an aerodynamic shape.

As to claim 20, the inner suface of the housing (50) of Stimpson et al. (fig.7a) proximal to the ejection head (62) and extending to the outlet (81) is contoured (see curved inner surface of housing 50 in fig.7a) to minimize turbulence.

Response to Arguments

3. Applicant's arguments with respect to claims 1-24 have been considered but are moot in view of the new ground(s) of rejection.

4. Applicant's arguments filed 04/08/2004 have been fully considered but they are not persuasive. Applicant's assertion that Michaels et al. physically eject liquid particles into the air stream is noted; however, this feature does not preclude Michaels et al. from being appropriately applied as prior art in combination with Stimpson et al. because Michaels et al. generate aerosol particles by physically ejecting a liquid through apertures within porous body (11) in an effort to control aerosol particle size and control depth of deposition of particles within a patient's respiratory system (col.4, lines 1-62).

Conclusion

5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AARON J. LEWIS whose telephone number is (703) 308-0716. The examiner can normally be reached on 9:30AM-6:00PM M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, HENRY A. BENNETT can be reached on (703) 308-0101. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AARON J. LEWIS
Primary Examiner
Art Unit 3743

Aaron J. Lewis
June 28,2004

USPTO TO PROVIDE ELECTRONIC ACCESS TO CITED U.S. PATENT REFERENCES WITH OFFICE ACTIONS AND CEASE SUPPLYING PAPER COPIES

In support of its 21st Century Strategic Plan goal of increased patent e-Government, beginning in June 2004, the United States Patent and Trademark Office (Office or USPTO) will begin the phase-in of its E-Patent Reference program and hence will: (1) **provide downloading capability of the U.S. patents and U.S. patent application publications cited in Office actions** via the E-Patent Reference feature of the Office's Patent Application Information Retrieval (PAIR) system; and (2) **cease mailing paper copies of U.S. patents and U.S. patent application publications with Office actions** (in applications and during reexamination proceedings) except for citations made during the international stage of an international application under the Patent Cooperation Treaty (PCT). In order to use the new E-Patent Reference feature applicants must: (1) obtain a digital certificate and software from the Office; (2) obtain a customer number from the Office; and (3) properly associate patent applications with the customer number. Alternatively, copies of all U.S. patents and patent application publications can be accessed without a digital certificate from the USPTO web site, from the USPTO Office of Public Records, and from commercial sources. The Office will continue the practice of supplying paper copies of foreign patent documents and non-patent literature with Office actions. Paper copies of cited references will continue to be provided by the USPTO for international applications during the international stage.

Schedule

June 2004	TCs 1600, 1700, 2800 and 2900
July 2004	TCs 3600 and 3700
August 2004	TCs 2100 and 2600

All U.S. patents and U.S. patent application publications are available on the USPTO web site. However, a simple system for downloading the cited U.S. patents and patent application publications has been established for applicants, called the E-Patent Reference system. As E-Patent Reference and Private PAIR require participating applicants to have a customer number, retrieval software and a digital certificate, all applicants are strongly encouraged to contact the Patent Electronic Business Center to acquire these items. To be ready to use this system by June 1, 2004, contact the Patent EBC as soon as possible by phone at 866-217-9197 (toll-free), 703-305-3028 or 703-308-6845 or electronically via the Internet at ebc@uspto.gov.

Other Options

The E-Patent Reference function requires the applicant to use the secure Private PAIR system, which establishes confidential communications with the applicant. Applicants using this facility must receive a digital certificate, as described above. Other options for obtaining patents which do not require the digital certificate include the USPTO's free Patents on the Web program (http://www.uspto.gov/patft/index.html). The USPTO's Office of Public Records also supplies copies of patents for a fee (http://ebiz1.uspto.gov/oems25p/index.html). Commercial sources also provide U.S. patents and patent application publications.

For complete instructions see the Official Gazette Notice, USPTO TO PROVIDE ELECTRONIC ACCESS TO CITED U.S. PATENT REFERENCES WITH OFFICE ACTIONS AND CEASE SUPPLYING PAPER COPIES, on the USPTO web site.

NOTICE OF OFFICE PLAN TO CEASE SUPPLYING COPIES OF CITED U.S. PATENT REFERENCES WITH OFFICE ACTIONS, AND PILOT TO EVALUATE THE ALTERNATIVE OF PROVIDING ELECTRONIC ACCESS TO SUCH U.S. PATENT REFERENCES

Summary

The United States Patent and Trademark Office (Office or USPTO) plans in the near future to: (1) cease mailing copies of U.S. patents and U.S. patent application publications (US patent references) with Office actions except for citations made during the international stage of an international application under the Patent Cooperation Treaty and those made during reexamination proceedings; and (2) provide electronic access to, with convenient downloading capability of, the US patent references cited in an Office action via the Office's private Patent Application Information Retrieval (PAIR) system which has a new feature called "E-Patent Reference." Before ceasing to provide copies of U.S. patent references with Office actions, the Office shall test the feasibility of the E-Patent Reference feature by conducting a two-month pilot project starting with Office actions mailed after December 1, 2003. The Office shall evaluate the pilot project and publish the results in a notice which will be posted on the Office's web site (www.USPTO.gov) and in the Patent Official Gazette (O.G.). In order to use the new E-Patent Reference feature during the pilot period, or when the Office ceases to send copies of U.S. patent references with Office actions, the applicant must: (1) obtain a digital certificate from the Office; (2) obtain a customer number from the Office, and (3) properly associate applications with the customer number. The pilot project does not involve or affect the current Office practice of supplying paper copies of foreign patent documents and non-patent literature with Office actions. Paper copies of references will continue to be provided by the USPTO for searches and written opinions prepared by the USPTO for international applications during the international stage and for reexamination proceedings.

Description of Pilot Project to Provide Electronic Access to Cited U.S. Patent References

On December 1, 2003, the Office will make available a new feature, E-Patent Reference, in the Office's private PAIR system, to allow more convenient downloading of U.S. patents and U.S. patent application publications. The new feature will allow an authorized user of private PAIR to download some or all of the U.S. patents and U.S. patent application publications cited by an examiner on form PTO-892 in Office actions, as well as U.S. patents and U.S. patent application publications submitted by applicants on form PTO/SB08 (1449) as part of an IDS. The retrieval of some or all of the documents may be performed in one downloading step with the documents encoded as Adobe Portable Document format (.pdf) files, which is an improvement over the current page-by-page retrieval capability from other USPTO systems.

Steps to Use the New E-Patent Reference Feature During the Pilot Project and Thereafter

Access to private PAIR is required to utilize E-Patent Reference. If you don't already have access to private PAIR, the Office urges practitioners, and applicants not represented by a practitioner, to take advantage of the transition period to obtain a no-cost USPTO Public Key Infrastructure (PKI) digital certificate, obtain a USPTO customer number, associate all of their pending and new application filings with their customer number, install no-cost software (supplied by the Office) required to access private PAIR and E-Patent Reference feature, and make appropriate arrangements for Internet access. The full instructions for obtaining a PKI digital certificate are available at the Office's Electronic Business Center (EBC) web page at: <http://www.uspto.gov/ebc/downloads.html>. Note that a notarized signature will be required to obtain a digital certificate.

To get a Customer Number, download and complete the Customer Number Request form, PTO-SB125, at: http://www.uspto.gov/web/forms/sb0125.pdf. The completed form can then be transmitted by facsimile to the Electronic Business Center at (703) 308-2840, or mailed to the address on the form. If you are a registered attorney or patent agent, then your registration number must be associated with your customer number. This is accomplished by adding your registration number to the Customer Number Request form. A description of associating a customer number with an application is described at the EBC web page at: http://www.uspto.gov/ebc/registration_pair.html.

The E-Patent Reference feature will be accessed using a new button on the private PAIR screen. Ordinarily all of the cited U.S. patent and U.S. patent application publication references will be available over the Internet using the Office's new E-Patent Reference feature. The size of the references to be downloaded will be displayed by E-Patent Reference so the download time can be estimated. Applicants and registered practitioners can select to download all of the references or any combination of cited references. Selected references will be downloaded as complete documents as Adobe Portable Document Format (.pdf) files. For a limited period of time, the USPTO will include a copy of this notice with Office actions to encourage applicants to use this new feature and, if needed, to take the steps outlined above in order to be able to utilize this new feature during the pilot and thereafter.

During the two-month pilot, the Office will evaluate the stability and capacity of the E-Patent Reference feature to reliably provide electronic access to cited U.S. patent and U.S. patent application publication references. While copies of U.S. patent and U.S. patent application publication references cited by examiners will continue to be mailed with Office actions during the pilot project, applicants are encouraged to use the private PAIR and the E-Patent Reference feature to electronically access and download cited U.S. patent and U.S. patent application publication references so the Office will be able to objectively evaluate its performance. The public is encouraged to submit comments to the Office on the usability and performance of the E-Patent Reference feature during the pilot. Further, during the pilot period registered practitioners, and applicants not represented by a practitioner, are encouraged to experiment with the feature, develop a proficiency in using the feature, and establish new internal processes for using the new access to the cited U.S. patents and U.S. patent application publications to prepare for the anticipated cessation of the current Office practice of supplying copies of such cited

references. The Office plans to continue to provide access to the E-Patent Reference feature during its evaluation of the pilot.

Comments

Comments concerning the E-Patent Reference feature should be in writing and directed to the Electronic Business Center (EBC) at the USPTO by electronic mail at eReference@uspto.gov or by facsimile to (703) 308-2840. Comments will be posted and made available for public inspection. To ensure that comments are considered in the evaluation of the pilot project, comments should be submitted in writing by January 15, 2004.

Comments with respect to specific applications should be sent to the Technology Centers' customer service centers. Comments concerning digital certificates, customer numbers, and associating customer numbers with applications should be sent to the Electronic Business Center (EBC) at the USPTO by facsimile at (703) 308-2840 or by e-mail at EBC@uspto.gov.

Implementation after Pilot

After the pilot, its evaluation, and publication of a subsequent notice as indicated above, the Office expects to implement its plan to cease mailing paper copies of U.S. patent references cited during examination of non provisional applications on or after February 2, 2004; although copies of cited foreign patent documents, as well as non-patent literature, will still be mailed to the applicant until such time as substantially all applications have been scanned into IFW.

For Further Information Contact

Technical information on the operation of the IFW system can be found on the USPTO website at http://www.uspto.gov/web/patents/ifw/index.html. Comments concerning the E-Patent Reference feature and questions concerning the operation of the PAIR system should be directed to the EBC at the USPTO at (866) 217-9197. The EBC may also be contacted by facsimile at (703) 308-2840 or by e-mail at EBC@uspto.gov.

Date. 12/1/03

Nicholas P. Godici
Commissioner for Patents

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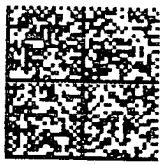

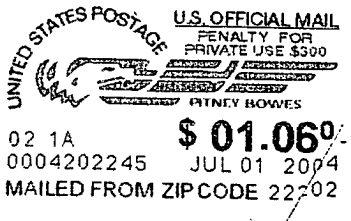

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